AUG 2 8 2009

510(k) SUMMARY **K090309**

Pre-market Notification for Lagis Endoscopic instruments

1. Submitter's Name

LAGIS ENTERPRISE CO. LTD.
No. 33, Lane 908, Sect. I, Jhongshan Road
Dajia, Taichung TAIWAN
Zip Code; 437
Contact Person: Joanne Chen, Manager, R&D

2. Name of Device

Common/Usual Name:	Electrosurgical instruments
Proprietary Name:	Lagis Endoscopic Instruments
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number:	CFR 878.4400
Product Code:	GEI

3. Predicate Device

Device Name	510(k) Number	Clearance Date
Auto Suture ENDO Clinch II	K951589	05/03/1995
ConMed Graspers & Scissors	K924469	04/07/1993

4. Device Description

The Lagis Endoscopic Instruments is a sterile, single use device having an insulated shaft with a diameter of 4.5-5.0 mm for use in 6mm and larger size trocar. The shaft can be rotated through the actions of a roller knob. A pair of plastic handles manipulates closing or opening of the tip scissors or graspers. An electrical connector allows for connection of the instrument to a generator for electrosurgical applications.

5. Indication for Use

The Lagis Endoscopic Instruments are designed for use in a variety of surgical procedures to facilitate grasping, dissecting, and transecting of tissues.

6. Technological Characteristics

Same as predicate devices, when the handles of the Lagis Endoscopic Instruments are compressed or released, the instrument jaws or scissor blades close or open accordingly. The rotating knob located on the handle can be turned for rotating the shaft 360 degrees in either direction. A monopolar electrical connector extending from the handle allows for connection with a standard cable to a proper HF generator. Due to different functional requirements, the tip can be of various designs such as straight scissors, curved scissors, and graspers, etc. The materials of construction are similar to the predicate devices and are satisfactorily tested for cytotoxicity, sensitization, intracutaneous reactivity and systematic toxicity per ISO 10993 and US FDA G-95 requirements

7. Performance Summary

Performance bench tests were carried out to verify design characteristics and to ensure that the device can be used as intended. The studies included testing of unit packaging integrity, functional and performance characteristics, as well as electrical safety of the devices. Test results demonstrated acceptable results with respect to predicate devices in tip rotation, shaft sturdiness, shaft dielectric strength, grasping force, and cutting capability of the instrument, etc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Lagis Enterprises Co., Ltd.
% Innomedtech LLC
Joseph J. Chang, Ph.D.
Consultant
7128 Staffordshire Street
Houston, Texas 77030

AUG 2 8 2009

Re: K090309
Trade Name: Lagis Endoscopic Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 20, 2009
Received: July 22, 2009

Dear Dr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K090309

Device Name:
Lagis Endoscopic Instruments

Indication for Use:
The Lagis Endoscopic Instruments are designed for use in a variety of surgical procedures to facilitate grasping, dissecting, and transecting of tissues.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090309